

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vignina 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/965,473	09/26/2001	Terry A. Guinan	P1046 US	2802	
7:	590 09/25/2003				
Medtronic AVE, Inc.			EXAMINER		
3576 Unocal Place Santa Rosa, CA 95403			BAXTER, JE	BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER	
			3731		
			DATE MAILED: 09/25/2003	ll	

Please find below and/or attached an Office communication concerning this application or proceeding.

~			ΛK			
•		Application No.	Applicant(s)			
Office Action Summary		09/965,473	GUINAN ET AL.			
		Examiner	Art Unit			
		Jessica R Baxter	3731			
Period fo	The MAILING DATE of this communication a	ppears on the cover sheet with	the correspondence address			
A SHO THE N - Exter after - If the - If NO - Failu	ORTENED STATUTORY PERIOD FOR REF MAILING DATE OF THIS COMMUNICATION resions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reperiod for reply is specified above, the maximum statutory perior to reply within the set or extended period for reply will, by state eply received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a reply reply within the statutory minimum of thirty (3 od will apply and will expire SIX (6) MONTH tute, cause the application to become ABAN	y be timely filed 10) days will be considered timely. S from the mailing date of this communication. DONED (35 U.S.C. § 133).			
1)⊠	Responsive to communication(s) filed on 0	8 July 2003 .				
2a)□	·	This action is non-final.				
3)□	Since this application is in condition for allo		rs, prosecution as to the merits is			
·	closed in accordance with the practice und on of Claims	er Ex parte Quayle, 1935 C.D.	11, 453 O.G. 213.			
4) 🖾	Claim(s) $1-18$ is/are pending in the application	ion.				
	4a) Of the above claim(s) is/are withd	rawn from consideration.				
5)	Claim(s) is/are allowed.					
6)⊠)⊠ Claim(s) <u>1-18</u> is/are rejected.					
7)	Claim(s) is/are objected to.					
•	Claim(s) are subject to restriction and	d/or election requirement.				
	ion Papers					
-	The specification is objected to by the Exami	_	Cuaminas			
10)[]`	The drawing(s) filed on is/are: a) ac					
11) 🗆 :	Applicant may not request that any objection to The proposed drawing correction filed on					
' '/-	If approved, corrected drawings are required in		approved by the Examiner.			
12) 🗆	The oath or declaration is objected to by the	· ·				
,—	under 35 U.S.C. §§ 119 and 120					
_	Acknowledgment is made of a claim for fore	eign priority under 35 U.S.C. & :	119(a)-(d) or (f).			
•	☐ All b)☐ Some * c)☐ None of:	g py amae, co otolo, g	V/ X=/ == X/*			
u)i	1.☐ Certified copies of the priority docume	ents have been received.				
	Certified copies of the priority docume	•	olication No			
* 6	Copies of the certified copies of the p application from the International See the attached detailed Office action for a l	riority documents have been re Bureau (PCT Rule 17.2(a)).	eceived in this National Stage			
	Acknowledgment is made of a claim for dome	•				
•) The translation of the foreign language					
	Acknowledgment is made of a claim for dome					
Attachmen	t(s)	_				
2) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s	5) Notice of Inf	mmary (PTO-413) Paper No(s) ormal Patent Application (PTO-152)			
S. Datast and T	rademark Office					

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1, 2, 4, 6, 7, 10, 11, 12, 13, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,048,350 to Vrba.

Regarding claims 1, 6, 7, 10 and 11, Vrba discloses a catheter comprising an elongate shaft (shaft 12) and a balloon having a flexible wall (balloon 16), an intermediate body (16B), proximal and distal cones (16A and 16C), proximal and distal ends, and at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone (FIG. 2 spaces 22), and a balloon expandable stent (stent 20).

Regarding claim 2, Vrba discloses that the circumferential groove has a shape selected from the C-shapes, U-shapes, W-shapes, and open-sided polygons (FIG. 2 spaces 22).

Regarding claims 4, 12, 13 and 18, Vrba discloses that the at least one circumferential groove is at least partially filled with a flexible material that is adhered to the balloon (Column3 lines 53-62).

Regarding claim 15, Vrba discloses a method comprising the steps of providing a catheter having an elongate shaft (shaft 12), mounting a balloon around a distal end of the shaft, collapsing the balloon around the catheter shaft (FIG. 1 and Column 3 lines 24-36),

Application/Control Number: 09/965,473

Art Unit: 3731

and mounting a balloon expandable stent in a radially compressed configuration around the intermediate body of the balloon (Column 3 lines 29-36).

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba '350 in view of U.S. Patent No.6,254,608 to Solar.

Vrba discloses the claimed invention except for the flexible material comprising a foamed material. Solar teaches that a foamed material is used for bonding the stent to the catheter to allow the stent to become embedded in the balloon in order to protect the anatomical passageways during delivery of the stent and prevent the stent from slipping without the use of a protective sheath (Column 3 line 44 – Column 4 line 2 and Column 5 lines 20-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon catheter of Vrba with the foamed material of Solar in order to protect the anatomical passageways during stent delivery and prevent the stent from slipping off the balloon without the use of a protective sheath.

1. Claims 3, 8, 9, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba '350 in view of U.S. Patent No. 6,293,959 to Miller et al.

Vrba discloses the claimed invention except for the balloon having a deflated profile where the distal and proximal cones have a larger deflated profile than the intermediate

Application/Control Number: 09/965,473

Art Unit: 3731

body. Miller teaches that the enlarged proximal and distal cones are provided to provide a nest portion for the stent so that friction is minimized and adverse contact between the ends of the stent and the vessel wall is minimized (Column 4 lines 36-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon of Vrba with the enlarged proximal and distal cones of Miller in order to provide a nest portion for the stent in order to minimize friction and adverse contact bet\ween the stent ends and the vessel wall.

Response to Arguments

1. Applicant's arguments filed July 8, 2003 have been fully considered but they are not persuasive.

Applicant argues that Vrba' 350 does not disclose a circumferential groove in the balloon wall adjacent a transition between the intermediate body and a cone. In FIG.2, there are clearly grooves in the balloon wall between the cone shape and the intermediate body. Applicant argues that these grooves are stent mounting bodies (24) that extend beyond the diameter of the balloon in the deflated condition. However, there are no claim limitations which require that the grooves are in both the inflated and deflated conditions of the balloon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization

Art Unit: 3731

where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9302 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter Examiner Art Unit 3731

jrb

September 21, 2003

MICHAEL J. MILANO

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700